UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-37906

ORGANOGENESIS HOLDINGS INC.
(Exact name of registrant as specified in its charter)

Delaware	**98-1329150**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

85 Dan Road
Canton, MA 02021
(Address of principal executive offices) (Zip Code)

(781) 575-0775
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, $0.0001 par value	**ORGO**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 1, 2019, the registrant had a total of 94,743,312 shares of its Class A common stock, $0.0001 par value per share, outstanding.

Organogenesis Holdings Inc.
Quarterly Report on Form 10-Q
For the Quarterly Period Ended September 30, 2019

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements may relate to, but are not limited to, expectations of our future results of operations, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities and the effects of competition, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These risks and other factors include, but are not limited to, those listed under "Risk Factors." In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "might," "would," "continue" or the negative of these terms or other comparable terminology. These forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and discussed elsewhere in this Form 10-Q. These forward-looking statements speak only as of the date of this Form 10-Q. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this Form 10-Q.

As used herein, except as otherwise indicated by context, references to "we," "us," "our," "the Company," "Organogenesis" and "ORGO" will refer to Organogenesis Holdings Inc. and its subsidiaries.

PART I—FINANCIAL INFORMATION
Item 1. Unaudited Consolidated Financial Statements.

ORGANOGENESIS HOLDINGS INC.
CONSOLIDATED BALANCE SHEETS
(unaudited)
(amounts in thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash	$ 22,974	$ 21,291
Restricted cash	185	114
Accounts receivable, net	34,383	34,077
Inventory	20,184	13,321
Prepaid expenses and other current assets	3,117	2,328
Total current assets	80,843	71,131
Property and equipment, net	44,254	39,623
Notes receivable from related parties	536	477
Intangible assets, net	22,314	26,091
Goodwill	25,539	25,539
Deferred tax asset	238	238
Other assets	916	579
Total assets	$ 174,640	$ 163,678
Liabilities and Stockholders' Equity		
Current liabilities:		
Deferred acquisition consideration	$ 5,000	$ 5,000
Redeemable common stock liability	—	6,762
Current portion of notes payable	—	2,545
Current portion of capital lease obligations	2,872	2,236
Accounts payable	28,251	19,165
Accrued expenses and other current liabilities	20,606	20,388
Total current liabilities	56,729	56,096
Line of credit	33,484	26,484
Notes payable, net of current portion	—	12,578
Term loan	49,599	—
Deferred rent	736	130
Capital lease obligations, net of current portion	14,893	15,418
Other liabilities	6,391	5,931
Total liabilities	161,832	116,637
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value; 400,000,000 shares authorized; 95,470,290 and 91,261,413 shares issued; 94,741,742 and 91,261,413 shares outstanding at September 30, 2019 and December 31, 2018, respectively.	9	9
Additional paid-in capital	179,408	177,272
Accumulated deficit	(166,609)	(130,240)
Total stockholders' equity	12,808	47,041
Total liabilities and stockholders' equity	$ 174,640	$ 163,678

The accompanying notes are an integral part of these unaudited consolidated financial statements.

ORGANOGENESIS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net revenue	$ 64,265	$ 50,769	$ 186,336	$ 129,850
Cost of goods sold	19,131	19,477	55,557	51,298
Gross profit	45,134	31,292	130,779	78,552
Operating expenses:				
Selling, general and administrative	49,475	38,583	147,325	114,483
Research and development	3,924	2,779	11,159	7,651
Write-off of deferred offering costs	—	—	—	3,494
Total operating expenses	53,399	41,362	158,484	125,628
Loss from operations	(8,265)	(10,070)	(27,705)	(47,076)
Other income (expense), net:				
Interest expense, net	(2,427)	(2,940)	(6,392)	(8,131)
Change in fair value of warrants	—	(50)	—	(299)
Loss on the extinguishment of debt	—	—	(1,862)	—
Other income (expense), net	(1)	9	11	12
Total other income (expense), net	(2,428)	(2,981)	(8,243)	(8,418)
Net loss before income taxes	(10,693)	(13,051)	(35,948)	(55,494)
Income tax expense	(48)	(27)	(108)	(82)
Net loss	(10,741)	(13,078)	(36,056)	(55,576)
Non-cash deemed dividend to warrant holders	(645)	—	(645)	—
Net loss attributed to common shareholders	$ (11,386)	$ (13,078)	$ (36,701)	$ (55,576)
Net loss per share attributed to common shareholders—basic and diluted	$ (0.12)	$ (0.19)	$ (0.40)	$ (0.83)
Weighted-average common shares outstanding—basic and diluted	92,276,858	69,496,280	91,182,233	66,745,895

The accompanying notes are an integral part of these unaudited consolidated financial statements.

ORGANOGENESIS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(unaudited)
(amounts in thousands, except share data)

	Three and Nine Months Ended September 30, 2018						
	Redeemable Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Organogenesis Holdings Inc. Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of June 30, 2018	728,548	$6,762	67,040,639	$ 6	$ 50,732	$ (107,907)	$ (57,169)
Proceeds from equity financing, net of issuance costs of $270	—	—	6,538,732	1	45,729	—	45,730
Exercise of stock options	—	—	15,757	—	33	—	33
Stock-based compensation expense	—	—	—	—	252	—	252
Net loss	—	—	—	—	—	(13,078)	(13,078)
Balance as of September 30, 2018	728,548	$6,762	73,595,128	$ 7	$ 96,746	$ (120,985)	$ (24,232)
Balance as of December 31, 2017	728,548	$6,762	66,983,139	$ 6	$ 50,086	$ (65,409)	$ (15,317)
Proceeds from equity financing, net of issuance costs of $270	—	—	6,538,732	1	45,729	—	45,730
Exercise of stock options	—	—	73,257	—	111	—	111
Stock-based compensation expense	—	—	—	—	820	—	820
Net loss	—	—	—	—	—	(55,576)	(55,576)
Balance as of September 30, 2018	728,548	$6,762	73,595,128	$ 7	$ 96,746	$ (120,985)	$ (24,232)

	Three and Nine Months Ended September 30, 2019						
	Redeemable Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Organogenesis Holdings Inc. Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of June 30, 2019	—	$ —	91,342,722	$ 9	$178,412	$ (155,223)	$ 23,198
Exercise of stock options	—	—	64,362	—	109	—	109
Exercise of common stock warrants			19,426	—	—	—	—
Common stock issued in warrant exchange	—	—	3,315,232	—	645	(645)	—
Stock-based compensation expense	—	—	—	—	242	—	242
Net loss	—	—	—	—	—	(10,741)	(10,741)
Balance as of September 30, 2019	—	$ —	94,741,742	$ 9	$179,408	$ (166,609)	$ 12,808
Balance as of December 31, 2018	728,548	$ —	91,261,413	$ 9	$177,272	$ (130,240)	$ 47,041
Adoption of ASC 606	—	—	—	—	—	332	332
Exercise of common stock warrants	—	—	74,052	—	628	—	628
Exercise of stock options	—	—	91,045	—	163	—	163
Common stock issued in warrant exchange	—	—	3,315,232	—	645	(645)	—
Stock-based compensation expense	—	—	—	—	700	—	700
Redemption of redeemable common stock placed into treasury	(728,548)	—	—	—	—	—	—
Net loss	—	—	—	—	—	(36,056)	(36,056)
Balance as of September 30, 2019	—	$ —	94,741,742	$ 9	$179,408	$ (166,609)	$ 12,808

The accompanying notes are an integral part of these unaudited consolidated financial statements.

ORGANOGENSIS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(amounts in thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$(36,056)	$(55,576)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,553	2,608
Amortization of intangible assets	4,526	2,752
Non-cash interest expense, net	196	595
Deferred interest expense	974	179
Deferred rent expense	606	42
Gain on disposal of property and equipment	—	(1)
Write-off of deferred offering costs	—	3,494
Benefit recorded for sales returns and doubtful accounts	(29)	(18)
Provision recorded for inventory reserve	809	2,068
Stock-based compensation	700	820
Change in fair value of warrant liability	—	299
Loss on extinguishment of debt	1,862	—
Changes in fair value of forfeiture rights	—	589
Changes in operating assets and liabilities:		
Accounts receivable	553	(815)
Inventory	(7,840)	145
Prepaid expenses and other current assets	(699)	(2,665)
Accounts payable	5,348	(508)
Accrued expenses and other current liabilities	85	(675)
Accrued interest—affiliate debt	—	2,859
Other liabilities	(715)	578
Net cash used in operating activities	(27,127)	(43,230)
Cash flows from investing activities:		
Purchases of property and equipment	(2,526)	(1,495)
Proceeds from disposal of property and equipment	—	1
Acquisition of intangible asset	(250)	—
Net cash used in investing activities	(2,776)	(1,494)
Cash flows from financing activities:		
Line of credit borrowings	7,000	2,616
Proceeds from term loan	50,000	—
Proceeds from long—term debt—affiliates	—	15,000
Proceeds from notes payable	—	5,000
Proceeds from equity financing	—	46,000
Repayment of notes payable	(17,585)	(10)
Proceeds from the exercise of stock options	163	111
Proceeds from the exercise of common stock warrants	628	—
Redemption of redeemable common stock placed into treasury	(6,762)	—
Principal repayments of capital lease obligations	(863)	(17)
Payment of debt issuance costs	(924)	(177)
Payment of equity issuance costs	—	(270)
Net cash provided by financing activities	31,657	68,253
Change in cash and restricted cash	1,754	23,529
Cash and restricted cash, beginning of period	21,405	2,358
Cash and restricted cash, end of period	$ 23,159	$ 25,887
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 5,922	$ 3,812
Cash paid for income taxes	$ 110	$ 62
Supplemental disclosure of non-cash investing and financing activities:		
Non-cash deemed dividend related to warrant exchange	$ 645	$ —
Debt and equity issuance costs included in accounts payable	$ 91	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 3,698	$ 39
Equipment acquired under capital lease	$ 973	$ —
Acquisition of intangible assets included in accrued expenses and other liabilities	$ 500	$ —

The accompanying notes are an integral part of these unaudited consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Organogenesis Holdings Inc. (formerly Avista Healthcare Public Acquisition Corp.) ("ORGO" or the "Company") is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. The majority of the existing and pipeline products in the Company's portfolio have Premarket Application approval, Business License Applicant approval or Premarket Notification 510(k) clearance from the United States Food and Drug Administration ("FDA"). The Company's customers include hospitals, wound care centers, government facilities, ambulatory service centers (ASCs) and physician offices. The Company operates in one operating and reportable segment.

Merger with Avista Healthcare Public Acquisition Corp

On December 10, 2018, Avista Healthcare Public Acquisition Corp., our predecessor company ("AHPAC"), consummated the previously announced merger (the "Avista Merger") pursuant to an Agreement and Plan of Merger, dated as of August 17, 2018 (as amended, the "Avista Merger Agreement"), by and among AHPAC, Avista Healthcare Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of AHPAC ("Avista Merger Sub") and Organogenesis Inc., a Delaware corporation ("Organogenesis Inc."). As a result of the Avista Merger and the other transactions contemplated by the Avista Merger Agreement, Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving the Avista Merger and becoming a wholly-owned subsidiary of AHPAC. AHPAC changed its name to Organogenesis Holdings Inc. (ORGO).

The Avista Merger was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, AHPAC was treated as the "acquired" company for accounting purposes. This determination was primarily based on Organogenesis Inc.'s equity holders having a majority of the voting power of the combined company, Organogenesis Inc. comprising the ongoing operations of the combined entity, Organogenesis Inc. comprising a majority of the governing body of the combined company, and Organogenesis Inc.'s senior management comprising the senior management of the combined company. Accordingly, for accounting purposes, the Avista Merger was treated as the equivalent of Organogenesis Inc. issuing stock for the net assets of AHPAC, accompanied by a recapitalization. The net assets of AHPAC were recorded at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Avista Merger are those of Organogenesis Inc.

Liquidity and Financial Conditions

In accordance with ASC 205-40, *Going Concern* ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company has incurred a recurring loss from operations since its inception and has funded its operations primarily with cash flow from product sales and proceeds from loans from affiliates and entities controlled by its affiliates, sales of its common stock and third-party debt. As of September 30, 2019, the Company had an accumulated deficit of $166.6 million and working capital of $24.1 million. During the nine months ended September 30, 2019, the Company has incurred net losses of $36.1 million and used $27.1 million of cash in operations. The Company expects to continue to generate operating losses for the foreseeable future as the Company expends resources to grow the organization to support the planned expansion of the business. The Company expects that its cash of $23.0 million as of September 30, 2019, plus cash flows from product sales and availability under the New Credit Agreement (see Note 9), which was entered into in March 2019, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of this quarterly report.

The Company may seek to raise additional funding through public and/or private equity financings, debt financings or other strategic transactions. There can be no assurance that the Company will be able to obtain additional debt or equity financing on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements have been prepared by management in accordance with accounting principles generally accepted in the United States of America ("GAAP") and in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements. While we believe that the disclosures presented are adequate in order to make the information not misleading, these unaudited quarterly financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "Annual Report").

The unaudited consolidated financial statements include the accounts and results of operations of Organogenesis Holdings Inc. and its wholly-owned or controlled subsidiaries. For periods prior to the closing of the Avista Merger on December 10, 2018, the notes to the unaudited consolidated financial statements have been updated to give effect to the Avista Merger. All intercompany balances and transactions have been eliminated in consolidation. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. In the opinion of management, the unaudited consolidated financial statements reflect all adjustments of a normal recurring nature necessary for a fair presentation of the Company's financial position, results of operations and cash flows at the dates and for the periods indicated. The results for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, any other interim periods, or any future year or period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported results of operations during the reporting period. Actual results could differ from those estimates.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," to the Consolidated Financial Statements included in the Annual Report. There have been no material changes to the significant accounting policies previously disclosed in the Annual Report other than as noted below.

Adoption of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606")

The Company adopted ASC 606 on January 1, 2019, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for the fiscal year 2019 reflect the application of ASC 606 guidance while the reported results for the fiscal year 2018 were prepared under the guidance of ASC Topic 605, *Revenue Recognition* ("ASC 605"). The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the transfer of control of the Company's products and provides enhanced disclosures to understand the nature, amount, timing, and uncertainty of revenues and cash flows arising from contracts with customers. In accordance with ASC 606, revenue is recognized when a customer obtains control of promised products. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products.

Historically, for certain customers, products were shipped in advance of the receipt of a purchase order and the Company recognized revenue on these products only upon receipt of the purchase order which is when the transaction price was deemed fixed and determinable. As control of these products has transferred upon use of the product in a procedure, the recognition of revenue is accelerated to the procedure date under ASC 606. The adoption of ASC 606 did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the three and nine months ended September 30, 2019.

Product Revenue

The Company generates revenue through the sale of Advanced Wound Care and Surgical & Sports Medicine products. There is a single performance obligation in all of the Company's contracts, which is the Company's promise to transfer the Company's product to customers based on specific payment and shipping terms in the arrangement. The entire transaction price is allocated to the single performance obligation. Product revenue is recognized when a customer obtains control of the Company's product which occurs at a point in time and may be upon shipment, procedure date, or delivery, based on the terms of the contract.

Reserves for Variable Consideration

Revenues from product sales are recorded net of reserves for variable consideration which includes but is not limited to product return, discounts, rebates and group purchasing organization ("GPO") fees that are offered within contracts between the Company and its customers relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed by its customers on the related sales and are recorded as reductions of accounts receivable or an establishment of a liability. Where appropriate, these estimates take into consideration a range of possible

outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract and is included in the net sales price to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately paid may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Product Returns

Consistent with industry practice, the Company generally offers customers a limited right of return for product purchased. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return reserves using its actual and historical return rates as well as factors that it becomes aware of that it believes could significantly impact its expected returns, including product recalls, pricing changes, or change in reimbursement rates. The Company does not record an asset for the returned product as the product is discarded upon receipt.

Rebates and Allowances

The Company provides certain customers with rebates and allowances that are explicitly stated in the Company's contracts, resulting in a reduction of revenue and the establishment of a liability that is included in accrued expenses in the accompanying consolidated balance sheets in the period the related product revenue is recognized.

GPO Fees

The Company pays fees to GPOs for administrative services that the GPOs perform in connection with the purchases of product by the GPO members. These fees are based on a contractually-determined percentage of the Company's applicable sales. The Company classifies these GPO fees as a reduction of revenue or as an operating expense based on the substance of the relationship of all parties involved in the transaction. For the three months ended September 30, 2019 and 2018, the Company recorded GPO fees of $880 and $581, respectively, as a direct reduction of revenue. For the nine months ended September 30, 2019 and 2018, the Company recorded GPO fees of $1,991 and $1,304, respectively, as a direct reduction of revenue.

Other Revenue Policies

Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Applying the practical expedient in paragraph ASC 606-10-32-18, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised products to the customer will be one year or less, which is the case with substantially all customers.

Applying the practical expedient in ASC 340-40-25-4, the Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in selling, general, and administrative expenses. The Company accounts for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products applying the practical expedient in ASC 606-10-25-18B.

Disaggregation of Revenue

The following table sets forth revenue by product category:

	Three Months Ended September 30,	
	2019	2018
Advanced Wound Care	$54,310	$43,597
Surgical & Sports Medicine	9,955	7,172
Total net revenue	$64,265	$50,769

	Nine Months Ended September 30,	
	2019	2018
Advanced Wound Care	$157,365	$109,711
Surgical & Sports Medicine	28,971	20,139
Total net revenue	$186,336	$129,850

For the three and nine months ended September 30, 2019, net PuraPly revenue totaled $31,755 and $86,893, respectively. For the three and nine months ended September 30, 2018, net PuraPly revenue totaled $17,872 and $41,261, respectively. For all periods presented, net revenue generated outside the US represented less than 1% of total net revenue.

Reclassification of Prior Period Balances

Reclassifications have been made to prior period amounts to conform to the current-year presentation of the reporting of deferred interest and principal on outstanding capital lease obligations and deferred tenant escalations as long-term liabilities on the consolidated balance sheets. The deferred interest and tenant escalation amounts were previously reported as accrued expenses on the consolidated balance sheets and the deferred principal on the capital lease obligations were recorded as part of the current portion of capital lease obligations on the consolidated balance sheet. These reclassifications have no effect on the reported net loss or equity for the periods ended September 30, 2018 or December 31, 2018.

Reclassification has been made to prior period amounts reported in the cash flows from operating activities section of the cash flow statement to conform to the current year presentation. The provision recorded for inventory reserve has been reduced by amounts not related to excess and obsolete inventory and change in inventory has been increased by a corresponding amount. The reclassification has no effect on the reported balance sheet, net loss or equity for the periods ended September 30, 2018 or December 31, 2018.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which applies to all leases and will require lessees to record most leases on the balance sheet but recognize expenses in a manner similar to the current standard. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which provides narrow amendments to clarify how to apply certain aspects of ASU 2016-02, and ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides adopters an additional transition method by allowing entities to initially apply ASU 2016-02, and subsequent related standards, at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Additionally, in March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements*, which clarifies the transition guidance related to interim disclosures provided in the year of adoption. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 for public business entities and interim periods within those years and for all other entities for years beginning after December 15, 2019. In July 2019, the FASB proposed to defer the effective date for nonpublic business entities to fiscal years beginning after December 15, 2020. The proposal was approved in October 2019. The Company is a public entity but took advantage of the relief provided for emerging growth companies to allow them to follow the private company adoption timelines and the Company expects to adopt this standard and the related improvements on January 1, 2021. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the transition date. A full retrospective application is prohibited. The Company continues to evaluate the impact of adopting this standard on its accounting policies, financial statements, business processes, systems and internal controls. The Company expects to recognize all of its leases with terms over twelve months on the balance sheet by recording a right-of-use asset and a corresponding lease liability.

Recently Adopted Accounting Pronouncements

In September 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This ASU expands the scope of *Topic 718, Compensation—Stock Compensation* to include share-based payments issued to nonemployees for goods or services. Under the new guidance, the existing employee guidance will apply to nonemployee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attribution of compensation cost. The cost of nonemployee awards will continue to be recorded as if the grantor had paid cash for the goods or services. The accounting standards update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted this standard, beginning with its financial reporting for the quarter ended June 30, 2019 due to the option activity to nonemployees in this quarter. The adoption of this standard did not have any material effect on the Company's consolidated financial statements or any component of stockholders' equity.

3. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2018. The redeemable common stock liability was settled in March 2019 as described below.

	Fair Value Measurements as of December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Redeemable common stock liability	$ —	$ —	$6,762	$6,762
	$ —	$ —	$6,762	$6,762

Redeemable Common Stock

On March 24, 2017, the Company issued 728,548 shares of Class A common stock in connection with the NuTech Medical acquisition (see Note 7), which were recorded at their fair value of $8.69 per share. These shares included a put right allowing the holder to put the shares back to the Company at an agreed-upon exercise price of $9.28 per share on March 24, 2019. The Company also had the right to call the shares at an agreed-upon exercise price of $9.28 per share prior to the second anniversary of the acquisition. These shares had been classified as temporary equity and had been accreted to the full redemption amount of $9.28 per share as the holder had the right to exercise the put right on March 24, 2019. These shares had the same rights and preferences as common stock. In December 2018, the Company received notification that the put option would be exercised. Accordingly, the Company reclassified the carrying value of the redeemable Class A common stock of $6,762 to a current liability as of December 31, 2018. The liability was settled in March 2019. As of September 30, 2019, the aforementioned 728,548 shares are held as treasury stock.

4. Accounts Receivable, Net

Accounts receivable consisted of the following:

	September 30, 2019	December 31, 2018
Accounts receivable	$ 37,318	$ 37,497
Less — allowance for sales returns and doubtful accounts	(2,935)	(3,420)
	$ 34,383	$ 34,077

The Company's allowance for sales returns and doubtful accounts was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Balance at beginning of period	$ 3,021	$ 2,853	$3,420	$ 3,225
Additions (reductions)	(56)	289	(29)	(18)
Write-offs	(30)	(51)	(456)	(116)
Balance at end of period	$ 2,935	$ 3,091	$2,935	$ 3,091

5. Inventories

Inventories, net of related reserves for excess and obsolescence, consisted of the following:

	September 30, 2019	December 31, 2018
Raw materials	$ 7,430	$ 4,711
Work in process	1,355	1,759
Finished goods	11,399	6,851
	$ 20,184	$ 13,321

Raw materials include various components used in the Company's manufacturing process. The Company's excess and obsolete inventory review process includes analysis of sales forecasts and historical sales as compared to inventory level, and working with operations to maximize recovery of excess inventory. During the three months ended September 30, 2019 and 2018, the Company charged $286 and $370, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations. During the nine months ended September 30, 2019 and 2018, the Company charged $809 and $2,068, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations. As of September 30, 2019 and December 31, 2018, the Company recorded a reserve for excess and obsolete inventory of $1,262 and $1,206, respectively.

6. Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2019	December 31, 2018
Leasehold improvements	$ 35,092	$ 34,345
Furniture, computers and equipment	46,038	44,752
	81,130	79,097
Accumulated depreciation and amortization	(64,977)	(62,435)
Construction in progress	28,101	22,961
	$ 44,254	$ 39,623

Depreciation expense was $792 and $861 for the three months ended September 30, 2019 and 2018, respectively. Depreciation expense was $2,553 and $2,608 for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019 and December 31, 2018, the Company had $21,689 of buildings under capital leases recorded within leasehold improvements. As of September 30, 2019 and December 31, 2018, the Company had $13,477 and $12,579 recorded within accumulated depreciation and amortization related to buildings under capital leases, respectively. Construction in progress primarily represents unfinished construction work on the 275 Dan Road SPE, LLC property and, more recently, improvements at the Company's leased facilities in Massachusetts.

7. Goodwill and Intangible Assets

Goodwill was $25,539 as of September 30, 2019 and December 31, 2018. There were no impairments recorded against goodwill during the three and nine months ended September 30, 2019 and year ended December 31, 2018.

In April, 2019, the Company purchased $750 of intangibles related to patent and know-how which were recorded within the developed technology category. The Company paid $250 at the time of the transaction. The remaining $500 is being paid over the eight quarters after the transaction closed and is recorded in accrued expenses and other current liabilities and other liabilities on the consolidated balance sheets. Identifiable intangible assets consisted of the following as of September 30, 2019:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	$30,570	$ (10,556)	$20,014
Trade names and trademarks	2,000	(592)	1,408
Independent sales agency network	4,500	(3,767)	733
Non-compete agreements	260	(101)	159
Total	$37,330	$ (15,016)	$22,314

Identifiable intangible assets consisted of the following as of December 31, 2018:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	$29,820	$ (8,454)	$21,366
Trade names and trademarks	2,000	(413)	1,587
Independent sales agency network	4,500	(1,569)	2,931
Non-compete agreements	260	(53)	207
Total	$36,580	$ (10,489)	$26,091

Amortization of intangible assets, calculated on a straight-line basis or over the estimated consumption of the intangible assets' economic benefits, were $1,529 and $918 for the three months ended September 30, 2019 and 2018, respectively, and $4,526 and $2,752 for the nine months ended September 30, 2019 and 2018, respectively.

8. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2019	December 31, 2018
Accrued personnel costs	$ 15,100	$ 15,218
Other	5,506	5,170
	$ 20,606	$ 20,388

9. Line of Credit and Notes Payable

Line of credit and notes payable consisted of the following:

	September 30, 2019	December 31, 2018
Line of credit	$ 33,484	$ 26,484
Term loan	50,000	—
Less debt discount and debt issuance cost	(401)	—
less current maturities	—	—
Term loan, net of debt discount and debt issuance cost	$ 49,599	$ —
Notes payable	—	15,885
Less debt discount and debt issuance cost	—	(762)
less current maturities	—	(2,545)
Notes payable, net of debt discount and debt issuance cost	$ —	$ 12,578

New Credit Agreement

In March 2019, the Company and its subsidiaries, Organogenesis Inc. and Prime Merger Sub, LLC (collectively, and jointly and severally, "Borrower"), and Silicon Valley Bank ("SVB"), as Administrative Agent, Issuing Lender and Swingline Lender, and the several other lenders thereto (the "Lenders") entered into a Credit Agreement (the "New Credit Agreement") providing for a term loan (the "Term Loan Facility") and a revolving credit facility (the "Revolving Facility", and together with the Term Loan Facility, the "Debt Facility") in an aggregate principal amount of $100,000.

The Term Loan Facility is structured in three tranches, as follows: (i) the first tranche of $40,000 was made available to Borrower and fully funded on March 14, 2019; (ii) the second tranche of $10,000 was made available to Borrower in September 2019 upon: (a) Borrower's demonstrated compliance with the financial covenants in the New Credit Agreement and (b) Borrower's achievement of trailing twelve month Consolidated Revenue of not less than $221,250 and a trailing three month Adjusted EBITDA (as defined in the New Credit Agreement) loss not in excess of $5,000; and (iii) the third tranche of $10,000 would be available to Borrower until March 31, 2020 subject to the Lenders' confirmation of Borrower's compliance with the financial covenants in the New Credit Agreement through December 31, 2019 and Borrower's achievement of trailing twelve month Consolidated Revenue not less than $231,500. The interest rate for term loan advances made under the Term Loan Facility is a per annum interest rate equal to 3.75% above the Wall Street Journal Prime Rate. The New Credit Agreement requires Borrower to make monthly interest-only payments on outstanding balances under the Term Loan Facility through February 2021. Thereafter, each term loan advance will be repaid in thirty-six equal monthly installments of principal, plus accrued interest, with the Term Loan Facility maturing on March 1, 2024 (the "Term Loan Maturity Date").

Borrower's final payment on the Term Loan Facility, due on the Term Loan Maturity Date, will include all outstanding principal and accrued and unpaid interest under the Term Loan Facility, plus a final payment (the "Final Payment") equal to the original aggregate principal amount of the Term Loan Facility multiplied by 6.25%. Borrower may prepay the Term Loan Facility, subject to paying the Prepayment Premium (described below) and the Final Payment. The Prepayment Premium is equal to 3.00% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs on or prior to the one year anniversary of the closing, 2.00% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs after such one year anniversary and prior to the second anniversary of the closing, and 1.00% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs after the two year anniversary but prior to the three year anniversary of the closing, and 0% thereafter. Once repaid, amounts borrowed under the Term Loan Facility may not be re-borrowed.

The Revolving Facility is equal to the lesser of $40,000 and the amount determined by the Borrowing Base, which is defined as a percentage of the Company's book value of qualifying finished goods inventory and eligible accounts receivable. The interest rate for advances under the Revolving Facility is a floating per annum interest rate equal to the Wall Street Journal Prime Rate. In the event that the aggregate amount of interest earned by the Lenders from the Revolving Facility in any given month is less than the interest that would have been earned if Borrower had average outstanding advances in an amount equal to 25% of the then-available Revolving Commitments (as defined in the New Credit Agreement) then Borrower must pay the Administrative Agent the Minimum Interest (as defined in the New Credit Agreement) in an amount equal to interest that would have accrued if average outstanding advances under the Revolving Facility had been 25% of the then-available Revolving Commitments less any interest actually earned by the Lenders. Borrower is also required to pay an unused line fee equal to 0.25% per annum, calculated based on the difference of $40,000 *minus* the greater of (i) the average balance outstanding under the Revolving Facility for such period and (ii) 25% of the then-available Revolving Commitments. The maturity date for advances made under the Revolving Facility is March 1, 2024.

Borrower may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal, unpaid accrued interest and a reduction or termination fee equal to 4.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs on or prior to the one year anniversary of the closing, 3.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after such one year anniversary and prior to the second anniversary of the closing, and 2.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after the two year anniversary but prior to the three year anniversary of the closing, and $0 thereafter.

Under the New Credit Agreement, Borrower is required to achieve Minimum Trailing Twelve Month Consolidated Revenue (as defined in the New Credit Agreement), tested quarterly, at the following levels: $200,000 for the trailing twelve months ending March 31, 2019; $213,500 for the trailing twelve months ending June 30, 2019; $221,250 for the trailing twelve months ending September 30, 2019; and $231,500 for the trailing twelve months ending December 31, 2019, with minimum revenue covenant levels for 2020 to be agreed between the Lenders and the Borrower no later than February 15, 2020. In addition, Borrower is required to maintain Minimum Liquidity (as defined in the New Credit Agreement) equal to the greater of (i) 6 months Monthly Burn (as defined in the New Credit Agreement) and (ii) $10,000.

As of September 30, 2019, the Company was in compliance with the financial covenants under the New Credit Agreement and had a total of $50,000 borrowings from the Term Loan Facility. The Company had an outstanding balance of $33,484 under the Revolving Facility with up to $6,516 (subject to the Borrowing Base) available for future revolving borrowings as of September 30, 2019. The Company incurred costs of $554 in connection with the Term Loan Facility, of which $462 is recorded as a reduction of the carrying value of the term loan on the Company's consolidated balance sheet and is being amortized to interest expense through the Term Loan Maturity Date and $92 related to the third tranche is recorded in other assets until the funding occurs. In connection with the Revolving Facility, the Company incurred costs of $370, which are recorded as other assets and amortized to interest expense through March 1, 2024.

Future payments of Term Loan Facility, as of September 30, 2019, are as follows for the calendar years ended December 31:

2019	$ —
2020	—
2021	13,888
2022	16,667
2023	16,667
2024	2,778
Total	$50,000

Credit Agreement

On March 21, 2017, the Company entered into a credit agreement (the "Credit Agreement") with SVB whereby SVB agreed to extend to the Company a revolving credit facility in an aggregate amount not to exceed $30,000 with a letter of credit sub-facility and a swing line sub-facility as a sublimit of the revolving loan facility. The amount available to borrow under both sub-facilities was dependent on a borrowing base, which was defined as a percentage of the Company's book value of qualifying finished goods and eligible accounts receivable. In April 2018, the Company further amended its Credit Agreement in order to receive additional funding of $5,000 through a term loan. The amendment increased the commitment under the Credit Agreement to an aggregate amount not to exceed $35,000, consisting of a term loan not to exceed $5,000 and a revolving loan not to exceed $30,000. In December 2018, the Company fully repaid and canceled the term loan including the outstanding principal and accrued and unpaid interest. As of December 31, 2018, the Company had borrowed an aggregate of $26,484 under the revolving credit facility and the total amount available for future revolving borrowings was $3,516.

On March 14, 2019, $26,541, representing all outstanding unpaid principal and accrued interest relating to the revolving borrowing due under the Credit Agreement, was rolled into the New Credit Agreement.

Master Lease Agreement

On April 28, 2017, the Company entered into the Master Lease Agreement (the "ML Agreement") with Eastward Fund Management LLC that allowed the Company to borrow up to $20,000 on or prior to June 30, 2018. Of the allowable amount, the Company borrowed a total of $16,000. If the Company elected to prepay the loan or terminated the loan early within the first 24 months, the Company was required to pay an additional 3% of the outstanding principal and any accrued and unpaid interest and fees. This prepayment fee decreased to 2% after the first 24 months. A final payment fee of 6.5% multiplied by the principal amount of the borrowings under the ML Agreement was due upon the earlier to occur of the first day of the final payment term month or prepayment of all outstanding principal. In March 2019, upon entering into the New Credit Agreement, the Company paid an aggregate amount of $17,649 due under the ML Agreement, including unpaid principal, accrued interest, final payment, and early termination penalty, with proceeds from the New Credit Agreement, and the ML Agreement was terminated. Upon termination of the ML Agreement, the Company recognized $1,862 as loss on the extinguishment of the loan.

10. Stockholders' Equity

Common Stock

As of September 30, 2019, the authorized capital stock of the Company included 400,000,000 shares of Class A common stock, $0.0001 par value. 95,470,290 shares of Class A common stock were issued as of September 30, 2019 which includes 728,548 shares that were reacquired in connection with the redemption of redeemable shares in March 2019. See Note 3.

At September 30, 2019 and December 31, 2018, the Company has reserved the following shares of Class A common stock for future issuance:

	September 30, 2019	December 31, 2018
Shares reserved for issuance for outstanding options	6,588,000	6,590,195
Shares reserved for issuance for future option grant	9,008,996	9,108,996
Shares reserved for issuance under the warrants	—	17,732,700
Total shares of authorized common stock reserved for future issuance	15,596,996	33,431,891

Warrant Exchange and Warrant Exercise

On July 22, 2019, the Company made an exchange offer (the "Exchange Offer") to all holders of the Company's 30.9 million outstanding warrants, that were issued in connection with the Company's initial public offering pursuant to a prospectus dated October 10, 2016 (the "Public Warrants"), to exchange 0.095 shares of Class A common stock for each Public Warrant tendered. On August 16, 2019, the expiration date of the Exchange Offer, a total of 29,950,150 warrants were tendered, resulting in the issuance of 2,845,280 shares of common stock.

On August 19, 2019, the Company executed an amendment to the warrant agreement, dated October 10, 2016, governing its outstanding Public Warrants to provide the Company with the right to require the Public Warrants holders to exchange one share of their Public Warrant for 0.0855 shares of the Company's Class A common stock. Pursuant to the amendment, the Company issued 80,451 additional shares in exchange for all remaining untendered Public Warrants.

Pursuant to the terms of the Company's previously announced Warrant Exchange Agreement dated July 12, 2019, with Avista Capital Partners IV L.P., and Avista Capital Partners IV (Offshore), L.P. (collectively, the "PIPE Investors"), the Company issued an aggregate of 389,501 shares of Class A common stock, to the PIPE Investors, at the same exchange ratio offered to the Public Warrant holders in the Exchange Offer, in exchange for an aggregate of 4,100,000 private placement warrants.

On August 13, 2019, Massachusetts Capital Resource Company and Life Insurance Community Investment Initiative, LLC (the "Lender Warrant Holders") net exercised outstanding warrants to purchase an aggregate of 182,700 shares of the Company's Class A common stock at an exercise price of $3.95 per share. The Company issued an aggregate of 19,426 shares of common stock in connection with this transaction.

As a result of these transactions, the Company issued an aggregate of 3,334,658 shares of common stock, representing approximately 3% of the total Class A common stock outstanding after such issuances. As of September 30, 2019, no warrants were outstanding.

As the fair value of the warrants exchanged in the warrant exchange transactions immediately prior to the exchanges was less than the fair value of the common stock issued, the Company recorded a non-cash deemed dividend of $0.6 million for the incremental fair value provided to the warrant holders in the three months ended September 30, 2019.

11. Stock-Based Compensation

Stock Incentive Plans

2018 Stock Incentive Plan

On November 28, 2018, the board of directors of the Company adopted, and on December 10, 2018 the Company's stockholders approved, the Organogenesis 2018 Equity and Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are to provide long-term incentives and rewards to the Company's employees, officers, directors and other key persons (including consultants), to attract and retain persons with the requisite experience and ability, and to more closely align the interests of such employees, officers, directors and other key persons with the interests of the Company's stockholders.

The 2018 Plan authorizes the Company's board of directors or a committee of not less than two independent directors (in either case, the "Administrator") to grant the following types of awards: non-statutory stock options; incentive stock options; restricted stock awards; restricted stock units; stock appreciation rights; unrestricted stock awards; performance share awards; and dividend equivalent rights. The 2018 Plan is administered by the Company's board of directors.

As of September 30, 2019, a total of 9,198,996 shares of Class A common stock have been authorized to be issued under the 2018 Plan (subject to adjustment in the case of any stock dividend, stock split, reverse stock split, or similar change in capitalization of the Company). As of September 30, 2019, options to purchase 190,000 shares of Class A common stock were outstanding under the 2018 Plan. No other awards have been issued under the 2018 Plan.

2003 Stock Incentive Plan

The Organogenesis 2003 Stock Incentive Plan (the "2003 Plan"), provides for the Company to issue restricted stock awards, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees. Restricted stock awards and non-statutory stock options may be granted to employees, members of the board of directors, outside advisors and consultants of the Company.

As of the closing of the Avista Merger on December 10, 2018, a total of 7,176,715 shares of Class A common stock were issuable upon exercise of outstanding options under the 2003 Plan. Effective as of the closing of the Avista Merger on December 10, 2018, no additional awards may be made under the 2003 Plan and as a result (i) any shares in respect of stock options that are expired or terminated under the 2003 Plan without having been fully exercised will not be available for future awards; (ii) any shares in respect of restricted stock that are forfeited to, or otherwise repurchased by the Company, will not be available for future awards; and (iii) any shares of common stock that are tendered to the Company by a participant to exercise an award will not be available for future awards.

Following the closing of the Avista Merger, the 2003 Plan is administered by the Company's board of directors.

Stock-Based Compensation Expenses

Stock options awarded under the 2018 Plan and the 2003 Plan expire 10 years after the grant date and typically vest over four or five years.

Stock-based compensation expense was $242 and $252 for the three months ended September 30, 2019 and 2018, respectively, and was $700 and $820 for the nine months ended September 30, 2019 and 2018, respectively. The total amount of stock-based compensation expenses was included within selling, general and administrative on the consolidated statements of operations.

Stock Option Valuation

The stock options granted during the nine months ended September 30, 2019 and September 30, 2018 were 100,000 and 78,111, respectively. The assumptions that the Company used to determine the grant-date fair value of stock options granted during these periods were as follows, presented on a weighted-average basis:

	September 30, 2019	September 30, 2018
Risk-free interest rate	2.24%	2.74%
Expected term (in years)	6.50	5.82
Expected volatility	42.7%	42.9%
Expected dividend yield	0.0%	0.0%
Exercise price	$ 7.08	$ 5.40
Underlying stock price	$ 7.08	$ 5.40

These assumptions resulted in an estimated weighted-average grant-date fair value per share of stock options granted during the nine months ended September 30, 2019 and 2018 of $3.24 and $2.39, respectively.

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2018 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	7,266,185	$ 1.92	5.89	$ 33,909
Granted	100,000	7.08		
Canceled / forfeited	(11,150)	2.87		
Exercised	(91,045)	1.77		382
Outstanding as of September 30, 2019	7,263,990	1.99	5.31	33,359
Options exercisable as of September 30, 2019	5,736,926	1.59	4.69	28,546
Options vested or expected to vest as of September 30, 2019	7,025,841	$ 1.91	5.20	$ 32,797

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class A common stock for those stock options that had exercise prices lower than the fair value of the Company's Class A common stock.

The total fair value of options vested during the nine months ended September 30, 2019 and 2018 was $538 and $503, respectively.

As of September 30, 2019, the total unrecognized stock compensation expense was $1,444 and is expected to be recognized over a weighted-average period of 2.59 years.

As of September 30, 2019, there were partial recourse notes outstanding totaling $635. These notes were taken by a former executive to exercise his stock options (see Note 14) and the notes were secured with the 675,990 shares held by the former executive. As the loans are still outstanding, the options are not considered exercised and are included within the options outstanding. Accordingly, the 675,990 shares are not considered outstanding and the par value and additional paid-in capital associated with these shares were deducted from equity in prior periods.

12. Net Loss per Share

The Company's potentially dilutive securities, which include redeemable common stock and stock options and warrants to purchase shares of Class A common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential shares of Class A common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to the common stockholders of Organogenesis Holdings Inc. for the periods indicated because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2019	2018
Options to purchase common stock	7,263,990	7,178,774
Redeemable common stock	—	728,548
Warrants to purchase common stock	—	1,561,485
	7,263,990	9,468,807

13. Commitments and Contingencies

Capitalized Leases

On January 1, 2013, the Company entered into capital lease arrangements with 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC for office and laboratory space in Canton, Massachusetts. 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC are related parties as the owners of these entities are also stockholders of the Company. The leases terminate on December 31, 2022 and each contains a renewal option for a five-year period with the rental rate at the greater of (i) rent for the last year of the prior term, or (ii) the then fair market value. Notice of the exercise of this renewal option is due one year prior to the expiration of the initial term. Aggregate annual lease payments are approximately $4,308 with future rent increases of 10% effective January 1, 2022.

The Company records the capital lease asset within property and equipment and the liability is recorded within the capital lease obligations on the consolidated balance sheets.

As of September 30, 2019 and December 31, 2018, the Company owed an aggregate of $10,336 and $10,293, respectively, of accrued but unpaid lease obligations. These accrued but unpaid lease obligations are subordinated to the New Credit Agreement and will not be paid until the debt under the New Credit Agreement is paid off. The principal portion of rent in arrears on the capital leases totaled $6,042 and $5,265 as of September 30, 2019 and December 31, 2018, respectively, and is included in the long-term portion of capital lease obligations. The interest portion of rent in arrears totaled $3,650 and $4,174 as of September 30, 2019 and December 31, 2018, respectively, and is included in other liabilities on the consolidated balance sheets.

In addition to rent, the Company is responsible for payment of all operating costs and common area maintenance under the aforementioned leases. As of September 30, 2019 and December 31, 2018, the Company owed $644 and $854, respectively, of operating and common area maintenance costs which are included in other liabilities on the consolidated balance sheets.

Effective April 1, 2019, the Company agreed to accrue interest on the accrued but unpaid lease obligations at an interest rate equal to the rate charged in the New Credit Agreement (see Note 9). The accrued interest is also subordinated to the New Credit Agreement and, as such, is included in other liabilities on the consolidated balance sheet. Interest accrued as of September 30, 2019 totaled $478.

Future obligations under capital leases in the aggregate and for the next five years is as follows:

2019 (remaining three months)	$ 1,180
2020	4,721
2021	4,721
2022	4,945
2023	—
Thereafter	9,692
	25,259
Less amount representing interest	(7,494)
Present value of minimum lease payments	17,765
Less current maturities	(2,872)
Long-term portion	$14,893

Operating Leases

The Company leases vehicles for certain employees and have fleet services agreements for service on these vehicles. The minimum lease term for each newly leased vehicle is one year with three consecutive one-year renewal terms.

In March 2014, in conjunction with the acquisition of Dermagraft from Shire plc, the Company entered into a rental sublease agreement for certain operating and office space in California. The original sublease agreements called for escalating monthly rental payments and were set to expire in January 2017. These sublease agreements were renegotiated in 2016 and subsequently extended through 2021.

In March 2019, the Company entered into an agreement to lease approximately 43,850 square feet of office and laboratory space in Norwood, Massachusetts. Pursuant to the lease agreement, the rent commencement date will be February 1, 2020. The initial lease term is ten years from the rent commencement date and includes an option for an early extension term of five years which is exercisable during the first two years after the rent commencement date. In addition to the early extension term, the lease provides the Company with an option to extend the lease term for a period of ten years, in addition to the five-year early extension term, if exercised, at rental rates equal to the then fair market value. Annual lease payments during the first year are $1,052 with increases of $44 each year during the initial ten-year lease term, an increase of $44 during the first year of the early extension term and $33 during year two through five of the early extension term. Upon execution of the agreement, the Company delivered a security deposit in the form of a letter of credit of $526 to the landlord. Following 36 months from the rent commencement date, the security deposit may be reduced by $263.

Operating lease expenses were $1,766 and $1,218 for the three months ended September 30, 2019 and 2018, respectively, and $4,993 and $3,630 for the nine months ended September 30, 2019 and 2018, respectively.

Future minimum lease payments due under noncancelable operating lease agreements as of September 30, 2019 are as follows:

2019 (remaining three months)	$ 1,218
2020	5,714
2021	5,053
2022	2,558
2023	1,180
Thereafter	8,123
	$23,846

Royalty Commitments

The Company entered into a license agreement with a university for certain patent rights related to the development, use, and production of one of its advanced wound care products. Under this agreement, the Company incurred a royalty based on a percentage of net product sales, for the use of these patents until the patents expired, which was in November 2006. Accrued royalties totaled $1,187 as of September 30, 2019 and December 31, 2018, and are classified as part of accrued expenses on the Company’s consolidated balance sheets. There was no royalty expense incurred during the three and nine months ended September 30, 2019 and 2018 related to this agreement.

In October 2017, the Company entered into a license agreement to resolve a patent infringement claim by a third party. Under the license agreement, the Company is required to pay royalties based on a percentage of net sales of the licensed product that occur, after December 31, 2016, through the expiration date of the underlying patent, subject to minimum royalty payment provisions. The

Company recorded royalty expense of $991 and $506 during the three months ended September 30, 2019 and 2018, respectively, within selling, general and administrative expenses on the consolidated statement of operations. The Company recorded royalty expense of $2,695 and $1,207 during the nine months ended September 30, 2019 and 2018, respectively, within selling, general and administrative expenses on the consolidated statement of operations.

Legal Proceedings

In conducting its activities, the Company, from time to time, is subject to various claims and also has claims against others. In management's opinion, the ultimate resolution of such claims would not have a material effect on the financial position of the Company. The Company accrues for these claims when amounts due are probable and estimable.

The Company accrued $542 and $1,000 as of September 30, 2019 and December 31, 2018, respectively, in relation to certain pending lawsuits.

The purchase price for NuTech Medical included $7,500 of future payments issued as deferred acquisition consideration. As of September 30, 2019, the Company has paid $2,500 in deferred acquisition consideration. The amount, if any, of the remaining $5,000 of deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical is currently in dispute. As of September 30, 2019, the Company recorded $842 of accrued interest related to the deferred acquisition consideration which is recorded in accrued expenses and other current liabilities. The Company has asserted certain claims for indemnification that would offset in whole or in part its payment obligation and the sellers of NuTech Medical have filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees.

14. Related Party Transactions

Capital lease obligations to affiliates are further described in Note 13.

During 2010, the Company's board of directors approved a loan program that permitted the Company to make loans to three executives of the Company (the "Employer Loans") to (i) provide them with liquidity ("Liquidity Loans") and (ii) fund the exercise of vested stock options ("Option Loans"). The Employer Loans mature with all principal and accrued interest due on the tenth anniversary of the issuance date of each subject loan, except that in certain circumstances, the Employer Loans may mature earlier. The borrower may prepay all or any portion of his Employer Loan at any time without premium or penalty. Interest on the Employer Loans accrues at various rates ranging from 2.30%—3.86% per annum, compounded annually. The Employer Loans are secured by stock and options in the Company held by the borrowers. With respect to the Liquidity Loans, the Company has no personal recourse against the borrowers beyond the pledged shares and options. As of September 30, 2019 and December 31, 2018, Liquidity Loans to two former executives remain outstanding with an aggregate principal balance of $2,350. As of September 30, 2019 and December 31, 2018, Option Loans to one former executive were outstanding with an aggregate principal balance of $635 and were secured by 675,990 shares of Class A common stock held by the former executive (see Note 11). The principal and part of the interest receivable under the Employer Loans were fully reserved with net principal and interest receivable of $536 and $477 as of September 30, 2019 and December 31, 2018, respectively, included in the notes receivable from related parties balance in the consolidated balance sheets.

In connection with the acquisition of NuTech Medical, the Company entered into an operating lease with Oxmoor Holdings, LLC, an entity that is affiliated with the former sole shareholder of NuTech Medical, related to the facility at NuTech Medical's headquarters in Birmingham, Alabama. Under the lease, the Company is required to make monthly rent payments of approximately $21 through December 31, 2020.

15. Subsequent Events

The Company has evaluated subsequent events through November 12, 2019, the date on which these consolidated financial statements were issued and has determined that there are no such events to report.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the Securities and Exchange Commission, or SEC, on March 18, 2019, as amended. Please refer to our note regarding forward-looking statements on page 2 of this Form 10-Q, which is incorporated herein by this reference.

Overview

Organogenesis is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Our products have been shown through clinical and scientific studies to support and in some cases accelerate tissue healing and improve patient outcomes. We are advancing the standard of care in each phase of the healing process through multiple breakthroughs in tissue engineering and cell therapy. Our solutions address large and growing markets driven by aging demographics and increases in comorbidities such as diabetes, obesity, smoking, and cardiovascular and peripheral vascular disease. We offer our differentiated products and in-house customer support to a wide range of health care customers including hospitals, wound care centers, government facilities, ASCs, and physician offices. Our mission is to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients while lowering the overall cost of care.

We offer a comprehensive portfolio of products in the markets we serve that address patient needs across the continuum of care. We have and intend to continue to generate data from clinical trials, real-world outcomes and health economics research that validate the clinical efficacy and value proposition offered by our products. The majority of the existing and pipeline products in our portfolio have PMA approval or 510(k) clearance from the FDA. Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, we believe that our data and regulatory approvals provide us a strong competitive advantage. Our product development expertise and multiple technology platforms provide a robust product pipeline, which we believe will drive future growth.

Historically we have concentrated our efforts in the Advanced Wound Care market. In 2017, we acquired NuTech Medical which further expanded our wound care portfolio and broadened our addressable market to include the Surgical & Sports Medicine market. We believe the expanded product portfolio facilitated by this acquisition is enhancing the ability of our sales representatives to reach and penetrate customer accounts, contributing to strong growth over time.

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds, primarily in the outpatient setting. We have a comprehensive portfolio of regenerative medicine products, capable of supporting patients from early in the wound healing process through to wound closure regardless of wound type. Our Advanced Wound Care products include Apligraf for the treatment of venous leg ulcers ("VLUs") and diabetic foot ulcers ("DFUs"); Dermagraft for the treatment of DFUs; PuraPly AM to address biofilm across a broad variety of wound types; and Affinity and NuShield to address a variety of wound sizes and types. We have a highly trained and specialized direct wound care sales force paired with exceptional customer support services.

In the Surgical & Sports Medicine market, we focus on products that support the healing of musculoskeletal injuries, including degenerative conditions such as osteoarthritis and tendonitis. We are leveraging our regenerative medicine capabilities in this attractive, adjacent market. Our Surgical & Sports Medicine products include ReNu for in-office joint and tendon applications; NuCel for bony fusion in the spine and extremities; NuShield and Affinity for surgical application in targeted soft tissue repairs; and PuraPly AM for surgical treatment of open wounds. We currently sell these products through independent agencies and our growing direct sales force.

On December 10, 2018, Avista Healthcare Public Acquisition Corp., our predecessor company ("AHPAC"), consummated the previously announced business combination pursuant to that certain Agreement and Plan of Merger, dated as of August 17, 2018 (as amended, the "Avista Merger Agreement"), by and among AHPAC, Avista Healthcare Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of AHPAC ("Avista Merger Sub") and Organogenesis Inc., a Delaware corporation ("Organogenesis Inc."). As a result of the transactions contemplated by the Avista Merger Agreement, Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving the merger (the "Avista Merger"). In addition, in connection with the business combination, and in accordance with Section 388 of the Delaware General Corporation Law and the Cayman Islands Companies Law (2018 Revision), AHPAC redomesticated as a Delaware corporation (the "Domestication"). After the Domestication, AHPAC changed its name to "Organogenesis Holdings Inc." As a result of the Avista Merger, Organogenesis Inc. became a wholly-owned subsidiary of Organogenesis Holdings Inc. For periods prior to the closing of the Avista Merger on December 10, 2018, the disclosure in Management's Discussion and Analysis of Financial Condition and Results of Operations has been updated to give effect to the Avista Merger.

For the nine months ended September 30, 2019, we generated $186.3 million of net revenue and had a net loss of $36.1 million compared to $129.9 million of net revenue and $55.6 million of net loss for the nine months ended September 30, 2018. We expect to incur operating losses for the foreseeable future as we expend resources as part of our efforts to grow our organization to support the planned expansion of our business. As of September 30, 2019, we had an accumulated deficit of $166.6 million. Our primary sources of capital to date have been from sales of our products, borrowings from related parties and institutional lenders and proceeds from the sale of our common stock. We operate in one segment of regenerative medicine.

Components of Our Consolidated Results of Operations

We adopted ASC 606 on January 1, 2019, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for the fiscal year 2019 reflect the application of ASC 606 guidance while the reported results for the fiscal year 2018 were prepared under the guidance of ASC 605. The impact of the adoption of ASC 606 on our opening balances and for the three and nine months ended September 30, 2019, in all financial statement line items impacted, was not significant from the amount that would have been reported under the previous guidance.

We consider a variety of performance and financial measures in assessing the performance of our business. We believe the items discussed below provide insight into the factors that affect these key measures.

Revenue

We derive our net revenue from our portfolio of Advanced Wound Care and Surgical & Sports Medicine products. We primarily sell our Advanced Wound Care products through direct sales representatives who manage and maintain the sales relationships with hospitals, wound care centers, government facilities, ASCs and physician offices. We primarily sell our Surgical & Sports Medicine products through third party agencies. As of September 30, 2019, we had approximately 240 direct sales representatives and approximately 145 independent agencies.

We recognize revenue from sales of our Advanced Wound Care and Surgical & Sports Medicine products when the customer obtains control of our product, which occurs at a point in time and may be upon shipment, procedure date, or delivery, based on the contractual terms of a contract. We record revenue net of a reserve for returns, discounts and GPO rebates, which represent a direct reduction to the revenue we recognize.

Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.

Included within our Advanced Wound Care revenue is our PuraPly product portfolio that consists of PuraPly and PuraPly AM. We launched PuraPly in mid-2015 and introduced PuraPly AM in 2016. In order to encourage the development of innovative medical devices, drugs and biologics, the Center for Medicare & Medicaid Services, or CMS, can grant new products an additional “pass through payment” in addition to the bundled payment amount for a limited period of no more than three years. Our PuraPly products were granted pass-through status from launch through December 31, 2017, which created an economic incentive for practitioners to use PuraPly over other skin substitutes. As a result, we saw increases in revenue related to our PuraPly portfolio in these periods. Beginning January 1, 2018, PuraPly AM and PuraPly transitioned to the bundled payment structure for skin substitutes, which provides for a two-tiered payment system in the hospital outpatient and ASC setting. The two-tiered Medicare payment system bundles payment for our Advanced Wound Care products (and all skin substitutes) into the payment for the procedure for applying the skin substitute, resulting in a single payment to the provider that includes reimbursement for both the procedure and the product itself. As a result of the transition to the bundled payment structure, total Medicare reimbursement for procedures using our PuraPly AM and PuraPly products decreased substantially. This reduction in reimbursement resulted in a substantial decrease in revenue from our PuraPly AM and PuraPly products during the first nine months of 2018 and had a negative effect on our business, results of operations and financial condition. On March 23, 2018, Congress passed, and the President signed into law, the Consolidated Appropriations Act of 2018, or the Act. The Act restored the pass-through status of PuraPly and PuraPly AM effective October 1, 2018. As a result, effective October 1, 2018, Medicare resumed making pass-through payments to hospitals using PuraPly and PuraPly AM in the outpatient hospital setting and in ASCs. PuraPly and PuraPly AM retain pass-through reimbursement status until September 30, 2020. Our other skin substitute products remain in the bundled payment structure.

Cost of goods sold, gross profit and gross profit margin

Cost of goods sold includes personnel costs, product testing costs, quality assurance costs, raw materials and product costs, manufacturing costs, and the costs associated with our manufacturing and warehouse facilities. The increases in our cost of goods sold correspond with the increases in sales units driven by the expansion of our sales force and sales territories, expansion of our product portfolio offerings, and the number of healthcare facilities that offer our products. We expect our cost of goods sold to increase due primarily to increased sales volumes.

Gross profit is calculated as net revenue less cost of goods sold and generally increases as revenue increases. Gross profit margin is calculated as gross profit divided by total net revenue. Our gross profit and gross profit margin are affected by product and geographic sales mix, realized pricing of our products, the efficiency of our manufacturing operations and the costs of materials used and fees charged by third-party manufacturers to produce our products. Regulatory actions, including healthcare reimbursement scenarios, which may require costly expenditures or result in pricing pressures, may decrease our gross profit and gross profit margin.

Selling, general and administrative expenses

Selling, general and administrative expenses generally include personnel costs for sales, marketing, sales support, customer support, and general and administrative personnel, sales commissions, incentive compensation, insurance, professional fees, depreciation, bad debt expense and information systems costs. We expect our selling, general and administrative expenses to continue to increase due to continued revenue growth, increased investments in market development and the geographic expansion of our sales forces.

Research and development expenses

Research and development expenses include personnel costs for our research and development personnel, expenses related to improvements in our manufacturing processes, enhancements to our currently available products, and additional investments in our product and platform development pipeline. Our research and development expenses also include expenses for clinical trials. We expense research and development costs as incurred. We generally expect that research and development expenses will increase as we continue to conduct clinical trials on new and existing products, move products through the regulatory pathway, add personnel to support product enhancements as well as to bring new products to market, and enhance our manufacturing process and procedures.

Other income (expense), net

Interest expense, net. Interest expense, net consists of interest on our outstanding indebtedness, including amortization of debt discount and debt issuance costs, net of interest income recognized.

Change in fair value of warrant liability. In connection with the 2016 Loans, we issued warrants to purchase our common stock to the lenders, who are affiliates of ours. We classified the warrants as a liability on our consolidated balance sheets because these warrants provided for down-round protection, which provided that the exercise price of the warrants be adjusted if we issued equity at a price that was below the exercise price of the warrants. The price of the warrants would also have been adjusted any time the price of another equity-linked instrument changed. The warrant liability was initially recorded at fair value and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as a component of other income (expense), net in the consolidated statements of operations. Changes in the fair value of the warrant liability were recognized until the warrants were exercised immediately prior to the closing of the Avista Merger on December 10, 2018.

Loss on the extinguishment of debt. In March 2019, upon entering into the New Credit Agreement, we paid an aggregate amount of $17,649 associated with the termination of the ML Agreement, including unpaid principal, accrued interest and an early termination penalty. We recognized $1,862 as loss on the extinguishment of the loan.

Income taxes

We account for income taxes using an asset and liability approach. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized.

In determining whether a valuation allowance for deferred tax assets is necessary, management analyzes both positive and negative evidence related to the realization of deferred tax assets and inherent in that, assesses the likelihood of sufficient future taxable income. Management also considers the expected reversal of deferred tax liabilities and analyzes the period in which these liabilities would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support realizability of the deferred tax assets. In addition, management considers whether it is more likely than not that the tax position will be sustained on examination by taxing authorities based on the technical merits of the position. Based on a consideration of the factors discussed above, including the fact that through the period ended September 30, 2019, our results reflected a three-year cumulative loss position, management has determined that a valuation allowance is necessary against the full amount of our net deferred tax assets, excluding alternative minimum tax credits. On December 22, 2017, the United States enacted new tax reform (“Tax Act”) and as a result, alternative minimum tax credits will be refundable beginning with the 2018 tax return. The alternative minimum tax credits will be realized, regardless of future taxable income, and thus no valuation allowance has been provided against this asset.

Results of Operations

The following table sets forth, for the periods indicated, our results of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net revenue	$ 64,265	$ 50,769	$186,336	$129,850
Cost of goods sold	19,131	19,477	55,557	51,298
Gross profit	45,134	31,292	130,779	78,552
Operating expenses:				
Selling, general and administrative	49,475	38,583	147,325	114,483
Research and development	3,924	2,779	11,159	7,651
Write-off of deferred offering costs	—	—	—	3,494
Total operating expenses	53,399	41,362	158,484	125,628
Loss from operations	(8,265)	(10,070)	(27,705)	(47,076)
Other income (expense), net:				
Interest expense, net	(2,427)	(2,940)	(6,392)	(8,131)
Change in fair value of warrants	—	(50)	—	(299)
Loss on the extinguishment of debt	—	—	(1,862)	—
Other income (expense), net	(1)	9	11	12
Total other income (expense), net	(2,428)	(2,981)	(8,243)	(8,418)
Net loss before income taxes	(10,693)	(13,051)	(35,948)	(55,494)
Income tax expense	(48)	(27)	(108)	(82)
Net loss	$(10,741)	$(13,078)	$ (36,056)	$ (55,576)

EBITDA and Adjusted EBITDA

The following table presents a reconciliation of net loss to Adjusted EBITDA for each of the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Net loss	$(10,741)	$(13,078)	$(36,056)	$(55,576)
Interest expense, net	2,427	2,940	6,392	8,131
Income tax expense	48	27	108	82
Depreciation	792	861	2,553	2,608
Amortization	1,529	918	4,526	2,752
EBITDA	(5,945)	(8,332)	(22,477)	(42,003)
Stock-based compensation expense	242	252	700	820
Change in contingent consideration forfeiture asset (1)	—	—	—	589
Change in fair value of warrant liability (2)	—	50	—	299
Loss on extinguishment of debt (3)	—	—	1,862	—
Write-off of deferred offering costs (4)	—	—	—	3,494
Merger transaction costs (5)	—	748	—	748
Exchange offer transaction costs (6)	916	—	916	—
Adjusted EBITDA	$ (4,787)	$ (7,282)	$(18,999)	$(36,053)

(1) The amount reflects the change in fair value of the common shares associated with the shares issued in connection with the acquisition of NuTech Medical that are forfeitable upon the occurrence of the FDA requiring approval of certain products acquired from NuTech Medical.

(2) In connection with our 2016 Loans, we classified the warrants issued to purchase our common stock to the lenders, who are affiliates of ours, as a liability on our consolidated balance sheet. Amounts reflect the change in fair value of the warrant liability.

(3) The amount reflects the amount of loss recognized on the extinguishment of the Master Lease Agreement upon repayment.

(4) The amount reflects the deferred offering costs in connection with an abandoned public offering.

(5) The amount reflects legal and professional fees incurred primarily in the quarter ended September 30, 2018 related directly to merger transaction costs which are being expensed as incurred.

(6) The amount reflects legal, advisory and other professional fees incurred in the quarter ended September 30, 2019 related directly to the warrant exchange transactions in Note 10.

Comparison of the Three Months and Nine Months Ended September 30, 2019 and 2018

Revenue

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Advanced Wound Care	$ 54,310	$ 43,597	$10,713	25%
Surgical & Sports Medicine	9,955	7,172	2,783	39%
Net revenue	$ 64,265	$ 50,769	$13,496	27%

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Advanced Wound Care	$157,365	$109,711	$47,654	43%
Surgical & Sports Medicine	28,971	20,139	8,832	44%
Net revenue	$186,336	$129,850	$56,486	44%

Net revenue from our Advanced Wound Care products increased by $10.7 million, or 25%, to $54.3 million in the three months ended September 30, 2019 from $43.6 million in the three months ended September 30, 2018. Net revenue from our Advanced Wound Care products increased by $47.7 million, or 43%, to $157.4 million in the nine months ended September 30, 2019 from $109.7 million in the nine months ended September 30, 2018. The increase in Advanced Wound Care net revenue was primarily attributable to additional sales personnel, PuraPly regaining pass-through reimbursement status for the two-year period effective October 1, 2018 and the continued growth in adoption of our amniotic products acquired in the NuTech Medical acquisition.

Net revenue from our Surgical & Sports Medicine products increased by $2.8 million, or 39%, to $10.0 million in the three months ended September 30, 2019 from $7.2 million in the three months ended September 30, 2018. Net revenue from our Surgical & Sports Medicine products increased by $8.8 million, or 44%, to $29.0 million in the nine months ended September 30, 2019 from $20.1 million in the nine months ended September 30, 2018. The increase in Surgical & Sports Medicine revenue was primarily due to the expansion of the sales force and penetration of existing and new customer accounts.

Included within net revenue is PuraPly revenue of $31.8 million and $17.9 million for the three months ended September 30, 2019 and 2018, respectively, and $86.9 million and $41.3 million for the nine months ended September 30, 2019 and 2018, respectively.

Cost of goods sold, gross profit and gross profit margin

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Cost of goods sold	$ 19,131	$19,477	$ (346)	(2%)
Gross profit	$ 45,134	$31,292	$13,842	44%
Gross profit%	70%	62%		

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Cost of goods sold	$ 55,557	$51,298	$ 4,259	8%
Gross profit	$130,779	$78,552	$52,227	66%
Gross profit%	70%	60%		

Cost of goods sold decreased by $0.3 million, or 2%, to $19.1 million in the three months ended September 30, 2019 from $19.5 million in the three months ended September 30, 2018. The decrease in cost of goods sold was primarily due to the manufacturing production process efficiencies, partially offset by increased unit volumes, additional manufacturing and quality control headcount, and facility improvement projects. Cost of goods sold increased by $4.3 million, or 8%, to $55.6 million in the nine months ended September 30, 2019 from $51.3 million in the nine months ended September 30, 2018. The increase in cost of goods sold was primarily due to increased unit volumes, additional manufacturing and quality control headcount, and facility improvement projects.

Gross profit increased by $13.8 million, or 44%, to $45.1 million in the three months ended September 30, 2019 from $31.3 million in the three months ended September 30, 2018. Gross profit increased by $52.2 million, or 66%, to $130.8 million in the nine months ended September 30, 2019 from $78.6 million in the nine months ended September 30, 2018. The increase in gross profit resulted primarily from increased sales volume due to the strength in our Advanced Wound Care and Surgical & Sports Medicine products, PuraPly regaining pass-through reimbursement status for the 2-year period effective October 1, 2018, and the resulting higher margins realized as a result of manufacturing efficiencies associated with our Advanced Wound Care products.

Research and Development Expenses

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Research and development	$ 3,924	$2,779	$1,145	41%
Research and development as a percentage of net revenue	6%	5%		

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Research and development	$11,159	$7,651	$3,508	46%
Research and development as a percentage of net revenue	6%	6%		

Research and development expenses increased by $1.1 million, or 41%, to $3.9 million in the three months ended September 30, 2019 from $2.8 million in the three months ended September 30, 2018. Research and development expenses increased by $3.5 million, or 46%, to $11.2 million in the nine months ended September 30, 2019 from $7.7 million in the nine months ended September 30, 2018. The increase in research and development expenses is primarily due to the increase in clinical research costs and increased headcount associated with our existing Advanced World Care and Surgical & Sports Medicine products and increase in product costs associated with our pipeline products not yet commercialized. We expect our research and development costs to continue to increase throughout 2019.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Selling, general and administrative	$ 49,475	$ 38,583	$10,892	28%
Selling, general and administrative as a percentage of net revenue	77%	76%		

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Selling, general and administrative	$147,325	$114,483	$32,842	29%
Selling, general and administrative as a percentage of net revenue	79%	88%		

Selling, general and administrative expenses increased by $10.9 million, or 28%, to $49.5 million in the three months ended September 30, 2019 from $38.6 million in the three months ended September 30, 2018. The increase in selling, general and administrative expenses is primarily due to an increase of $7.2 million related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, an increase of $1.8 million associated with marketing and promotional materials for our products, an increase of $0.9 million in legal, consulting fees and other costs associated with the ongoing operations of our business, an increase of amortization of $0.6 million associated with intangible assets amortized using the economic benefits method, and an increase of $0.4 million in royalties attributable to certain product sales.

Selling, general and administrative expenses increased by $32.8 million, or 29%, to $147.3 million in the nine months ended September 30, 2019 from $114.5 million in the nine months ended September 30, 2018. The increase in selling, general and administrative expenses is primarily due to an increase of $26.1 million related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, an increase of $1.3 million associated with marketing and promotional materials for our products, an increase of $2.9 million in legal, consulting fees and other costs associated with the ongoing operations of our business, an increase of amortization of $1.8 million associated with the intangible assets amortized using the economic benefits method, and an increase of $1.3 million in royalties attributable to certain product sales. These increases are partially offset by a decrease of $0.6 million related to the expiration of the forfeiture right asset in the prior year.

Other Income (Expense)

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Interest expense, net	$(2,427)	$(2,940)	$ 513	(17%)
Change in fair value of warrant liability	—	(50)	50	**
Other income (expense), net	(1)	9	(10)	**
Total other expense, net	$(2,428)	$(2,981)	$ 553	(19%)

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except for percentages)			
Interest expense, net	$(6,392)	$(8,131)	$ 1,739	(21%)
Change in fair value of warrant liability	—	(299)	299	**
Loss on the extinguishment of debt	(1,862)	—	(1,862)	**
Other income (expense), net	11	12	(1)	**
Total other expense, net	$(8,243)	$(8,418)	$ 175	(2%)

** not meaningful

Other expense, net, decreased by $0.6 million, or 19%, to $2.4 million in the three months ended September 30, 2019 from $3.0 million in the three months ended September 30, 2018. Interest expense, net, decreased to $2.4 million in the three months ended September 30, 2019 from $2.9 million in the three months ended September 30, 2018 primarily due to the repayment and conversion to equity of affiliate debt in connection with the Avista Merger. The decrease in the change in fair value of warrant liability is due to the exercise of the underlying warrants in connection with the Avista merger transaction.

Other expense, net, decreased by $0.2 million, or 2%, to $8.2 million in the nine months ended September 30, 2019 from $8.4 million in the nine months ended September 30, 2018. Interest expense, net, decreased by $1.7 million primarily due to the repayment and conversion to equity of affiliate debt in connection with the Avista Merger. Change in fair value of warrant liability decreased by $0.3 million due to the exercise of the underlying warrants in connection with the Avista merger transaction. The decreases are partially offset by $1.9 million increase in loss on the extinguishment of debt which reflects the write-off of unamortized debt discount upon repayment of the Master Lease Agreement as well as early payment penalties in March 2019.

Liquidity and Capital Resources

Since our inception, we have funded our operations and capital spending through cash flows from product sales, loans from affiliates and entities controlled by certain of our affiliates, third-party debt and proceeds from the sale of our capital stock. As of September 30, 2019, we had $23.0 million in cash, $24.1 million in working capital, and availability under both the Term Loan Facility and the Revolving Facility of the New Credit Agreement. We expect that our cash on hand as of September 30, 2019, plus availability under our New Credit Agreement, and cash flows from product sales, will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of this quarterly report.

Our primary uses of cash are working capital requirements, capital expenditures and debt service payments. Additionally, from time to time, we may use capital for acquisitions and other investing and financing activities. Working capital is used principally for our personnel as well as manufacturing costs related to the production of our products. Our working capital requirements vary from period-to-period depending on manufacturing volumes, the timing of shipments and the payment cycles of our customers and payers. Our capital expenditures consist primarily of building improvements, manufacturing equipment, and computer hardware and software.

To the extent additional funds are necessary to meet our long-term liquidity needs as we continue to execute on our business strategy, we anticipate that they will be obtained through the sales of product, incurrence of additional indebtedness, additional equity financings or a combination of these potential sources of funds, which may not be available on favorable terms, which could result in dilution to our stockholders and could require us to agree to covenants that limit our operating flexibility.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$(27,127)	$(43,230)
Net cash used in investing activities	(2,776)	(1,494)
Net cash provided by financing activities	31,657	68,253
Net change in cash and restricted cash	$ 1,754	$ 23,529

Operating Activities

During the nine months ended September 30, 2019, net cash used in operating activities was $27.1 million, resulting from our net loss of $36.1 million and net cash used in connection with changes in our operating assets and liabilities of $3.3 million, partially offset by non-cash charges of $12.2 million. Net cash used in changes in our operating assets and liabilities includes an increase in inventory of $7.8 million, an increase in prepaid expenses and other current assets of $0.7 million and a decrease in other liabilities of $0.7 million, all of which were partially offset by a decrease in accounts receivable of $0.6 million and an increase in accounts payable and accrued expenses and other current liabilities of $5.4 million.

During the nine months ended September 30, 2018, net cash used in operating activities was $43.2 million, resulting from our net loss of $55.6 million and net cash used in connection with changes in our operating assets and liabilities of $1.1 million, partially offset by non-cash charges of $13.4 million. Net cash used in changes in our operating assets and liabilities includes an increase in prepaid expenses and other current assets of $2.7 million, an increase in accounts receivable of $0.8 million, and a decrease in accounts payable and accrued expenses and other current liabilities of $1.2 million, all of which were partially offset by an increase in accrued interest – affiliate debt of $2.9 million, an increase in other liabilities of $0.6 million and an decrease in inventory of $0.1 million.

Investing Activities

During the nine months ended September 30, 2019, we used $2.8 million of cash in investing activities consisting of capital expenditures and an intangible asset purchase.

During the nine months ended September 30, 2018, we used $1.5 million of cash in investing activities consisting of capital expenditures.

Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was $31.7 million. This consisted primarily of $57.0 million in proceeds from the New Credit Agreement, and $0.8 million in proceeds from the exercise of common stock warrants and options. The net cash provided by financing activities was partially offset by the payment of the put option on redeemable common stock of $6.8 million, repayment of the Master Lease Agreement of $17.6 million, repayment of capital lease obligations of $0.9 million and the payment of $0.9 million related to debt issuance costs for the New Credit Agreement.

During the nine months ended September 30, 2018, net cash provided by financing activities was $68.3 million that consisted primarily of $46.0 million from the issuance of common stock, $15.0 million in related party borrowings, $5.0 million in notes payable borrowings, $2.6 million in net borrowings under our Credit Agreement and $0.1 million in proceeds from the exercise of common stock options, all of which were partially offset by the payment of debt and equity issuance costs of $0.4 million.

Indebtedness

2019 New Credit Agreement

On March 14, 2019, we and our subsidiaries, Organogenesis Inc. and Prime Merger Sub, LLC entered into a credit agreement with SVB and several other lenders, which we refer to as the New Credit Agreement. The New Credit Agreement provides for a revolving credit facility (the "Revolving Facility") of up to the lesser of $40.0 million and the amount determined by the Borrowing Base (as defined in the New Credit Agreement). Additionally, we entered into a $60.0 million term loan (the "Term Loan Facility") structured in three tranches. The first tranche of $40.0 million was made available to us and fully funded on March 14, 2019; (ii) the second tranche of $10.0 million was made available to us in September, 2019 upon our demonstrated compliance with the financial covenants in the New Credit Agreement and our achievement of trailing twelve month Consolidated Revenue of not less than $221.3 million and a trailing three month EBITDA (as defined in the New Credit Agreement) loss not in excess of $5.0 million; and (iii) the third tranche of $10.0 million would be available to us until March 31, 2020 subject to the lenders' confirmation of our compliance with the financial covenants in the New Credit Agreement through December 31, 2019 and our achievement of trailing twelve month Consolidated Revenue not less than $231.5 million.

We are required to comply with certain covenants and restrictions under the New Credit Agreement facilities. If we fail to comply with these requirements, the lenders will be entitled to exercise certain remedies, including the termination of the lending commitments and the acceleration of the debt payments under either or both of the Revolving Facility or the Term Loan Facility. Under the New Credit Agreement, we are required to achieve Minimum Trailing Twelve Month Consolidated Revenue (as defined in the New Credit Agreement), tested quarterly, at the following levels: $200.0 million for the trailing twelve months ending March 31, 2019; $213.5 million for the trailing twelve months ending June 30, 2019; $221.3 million for the trailing twelve months ending September 30, 2019; and $231.5 million for the trailing twelve months ending December 31, 2019, with minimum revenue covenant levels for 2020 to be agreed between the lenders and us no later than February 15, 2020. In addition, we are required to maintain Minimum Liquidity (as defined in the New Credit Agreement) equal to the greater of (i) 6 months Monthly Burn (as defined in the New Credit Agreement) and (ii) $10.0 million.

We satisfied the second tranche requirement for trailing twelve month Consolidated Revenue and a trailing three month Adjusted EBITDA and obtained the second tranche of $10.0 million borrowings under the New Credit Agreement in September 2019. As of September 30, 2019, we were in compliance with the financial covenants under the New Credit Agreement and we had outstanding borrowing under the Revolving Facility and Term Loan Facility of the New Credit Agreement of $33.5 million and $50.0 million, respectively.

2017 Credit Agreement

In March 2017, we entered into a credit agreement with SVB, which we refer to as the Credit Agreement. The Credit Agreement, as amended, provided for a revolving credit facility of up to $30.0 million and a term loan of up to $5.0 million. The term loan was repaid in full in December 2018. As of December 31, 2018, we had outstanding borrowing under the revolving credit facility of the Credit Agreement of $26.5 million. Upon entering into the New Credit Agreement, the outstanding amount due under the Credit Agreement was fully repaid and terminated.

Master Lease Agreement

In April 2017, we entered into the Master Lease Agreement (the "ML Agreement") with Eastward Fund Management LLC. As of December 31, 2018, we had outstanding borrowings of $15.9 million under the ML Agreement. Upon entering into the New Credit Agreement, the outstanding amount due under the ML Agreement was fully repaid and terminated.

NuTech Medical

As part of the consideration for the acquisition of NuTech Medical on March 24, 2017, we agreed to make four quarterly payments of $1.0 million during the first year following the closing, less a $0.5 million adjustment for working capital, and a payment of $4.0 million on the fifteen-month anniversary of the closing. As of September 30, 2019, $5.0 million remains payable and is accruing interest at a rate of 6% per annum. Refer to Note 13, "Commitments and Contingencies".

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations (1)	$ 23,846	$ 5,508	$ 8,475	$ 2,658	$ 7,205
Capital lease obligations (2)	25,259	4,721	9,662	10,876	—
Debt obligations (3)	108,501	6,489	37,520	64,492	—
Purchase commitments (4)	18,428	18,428	—	—	—
Deferred acquisition consideration (5)	5,842	5,842	—	—	—
Acquisition of intangible assets (6)	500	250	250	—	—
Total	$182,376	$ 41,238	$55,907	$78,026	$ 7,205

(1) Amounts in the table reflect minimum payments due for our lease of office space and vehicles under operating leases that expire between 2019 and 2030.

(2) Amounts in the table reflect the total cash payments on our capital lease obligations primarily related to the office and laboratory space in Canton, Massachusetts, including accrued interest of $3,650 for rent in arrears discussed in Note 13. The leases have a ten-year term and expire in December 2022.

(3) Amounts in the table reflect the contractually required principal and interest payable as of September 30, 2019 pursuant to outstanding borrowings under the 2019 New Credit Agreement. For the Term Loan Facility, the table reflects interest-only payments through February 2021 at an interest rate of 9.25%, as well as a final payment of $3.1 million due upon repayment of all outstanding amounts. For the Revolving Facility, the table reflects interest payments relating to the outstanding principal due in March 2024, calculated using an interest rate of 5.5%, which was the applicable interest rate as of September 30, 2019.

(4) Amounts in the table reflect purchase commitments to suppliers for raw materials and consumables to be utilized in the manufacturing process.

(5) Amounts in the table reflect deferred acquisition consideration payable to the sellers of NuTech Medical including interest accruing at a rate of 6% per annum.

(6) Amounts in the table reflect the remaining payments due related to the acquisition of intangible assets.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. Management bases its estimates, assumptions and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its estimates, assumptions and judgments on an ongoing basis. Historically, our critical accounting estimates have not differed materially from actual results. However, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our consolidated statements of operations, liquidity and financial condition. See also our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 for information about these accounting policies as well as a description of our other significant accounting policies.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards (such as ASU 2016-02, *Leases (Topic 842)*) and, as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the last day of the fiscal year following October 14, 2021, the fifth anniversary of our IPO, or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards as disclosed in Note 2 to our consolidated financial statements included in this Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to various market risks, including fluctuations in interest rates and variability in currency exchange rates. We have established policies, procedures and internal processes governing our management of market risk and the use of financial instruments to manage our exposure to such risk.

Interest Rate Risk

As of September 30, 2019, we had $50.0 million and $33.5 million of borrowings outstanding under the Term Loan Facility and the Revolving Facility, respectively. Borrowings under our Debt Facility bear interest at variable rates. Based on the principal amounts outstanding as of September 30, 2019, an immediate 10% change in the interest rate would not have a material impact on our debt-related obligations, financial position or results of operations.

Foreign Currency and Market Risk

The majority of our employees and our major operations are currently located in the United States. The functional currency of our foreign subsidiary in Switzerland is the U.S. dollar. We have, in the normal course of business, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period from the date that transactions are initiated and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Material Weaknesses on Internal Control over Financial Reporting

The Company's management, with the participation of its principal executive officer and principal financial officer, evaluated the effectiveness of its disclosure controls and procedures as of September 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission (the "SEC"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, our management has assessed the effectiveness of our internal control over financial reporting based on the criteria set forth in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

As previously disclosed under "Item 9A. Controls and Procedures" in our Annual Report on Form 10-K for our fiscal year ended December 31, 2018, we identified the following deficiencies that existed as of December 31, 2018 and continued to exist at September 30, 2019. A material weakness is a control deficiency or a combination of control deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.
- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose certain complex transactions, including the recapitalization and related debt extinguishment and conversion.

Because of the deficiencies noted above, in consultation with management, our principal executive officer and principal financial officer concluded that we did not maintain effective internal control over financial reporting and our disclosure controls and procedures were not effective as of both December 31, 2018 and September 30, 2019, based on the criteria in Internal Control—Integrated Framework (2013) issued by COSO.

Plans for Remediation of Material Weakness

Although the Company has made significant progress in remediating the aforementioned deficiencies, management did not perform sufficient control testing to conclude that the material weaknesses were remediated and therefore some of the control deficiencies continued to exist as of September 30, 2019. The Company is currently taking actions to remediate the deficiencies in its internal controls over financial reporting and is implementing additional processes and controls designed to address the underlying causes associated with the aforementioned deficiencies. During the period covered by this Quarterly Report on Form 10-Q, we continued to:

- add additional accounting resources who have the requisite background and knowledge in the application of GAAP;
- engage external experts to complement internal resources and to provide support related to more complex applications of GAAP;
- implement a new company-wide enterprise resource planning system and design effective financial and information technology general controls (ITGCs) over the system;
- formalize documentation of certain policies throughout the year;
- enhance our process in accounting for, and documenting our positions related to, our accounting topics throughout the year;
- work with an outside firm that is assisting management with:
    - enhancing the execution of our risk assessment activities by evaluating whether the design of our internal controls appropriately addresses changes in the business (including changes to people, processes and systems) that could impact our system of internal controls;
    - reviewing our current processes, procedures and systems to identify opportunities to enhance the design of each process and to include additional control activities that will ensure all transactions are properly recorded;
    - developing a monitoring protocol that will allow the company to validate the operating effectiveness of certain controls over financial reporting to gain assurance that such controls are present and functioning as designed. We will assess whether the company is sufficiently staffed to meet its design objectives for internal control over financial reporting and whether the appropriate resources are performing the control activities; and
- report regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies.

The Company believes these actions will be effective in remediating the deficiencies described above. As the Company continues to evaluate and work to improve its internal control over financial reporting, management may determine to take additional measures to address the deficiencies or determine to modify the remediation plan described above. Until the remediation steps set forth above are fully implemented and operating for a sufficient period of time, the material weaknesses described above will continue to exist.

Changes in Internal Control Over Financial Reporting

Other than in connection with executing upon the implementation of the remediation plan outlined above, there were no changes in our internal control over financial reporting during the period ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings. From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. These matters may include intellectual property, employment and other general claims. With respect to our outstanding legal matters, based on our current knowledge, we believe that the amount or range of reasonably possible loss will not, either individually or in the aggregate, have a material adverse effect on our business, consolidated financial position, results of operations, or cash flows. However, the outcome of such legal matters is inherently unpredictable and subject to significant uncertainties.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2018 includes a detailed discussion of our risk factors under the heading “Part I, Item 1A—Risk Factors.” Except as set forth below, there have been no material changes from such risk factors during the three months ended September 30, 2019. You should consider carefully the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2018, and all other information contained in or incorporated by reference in this Quarterly Report on Form 10-Q before making an investment decision. If any of the risks discussed in the Annual Report on Form 10-K or herein actually occur, they may materially harm our business, financial condition, operating results, cash flows or growth prospects. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition, operating results, cash flows or growth prospects and could result in a complete loss of your investment.

Currently, all of our currently marketed wound care products are assigned to the high cost bundle for purposes of Medicare reimbursement; it is not possible to predict, however, whether those products will continue to be assigned to the high cost bundle or the rates that will be paid for each bundle.

All of our Advanced Wound Care products are classified as “skin substitutes” for Medicare reimbursement purposes. In 2014, CMS instituted “bundled” payments in the hospital outpatient and ASC setting for skin substitutes using a two-tier payment system. The Medicare payment system bundles payment for our products (and all skin substitutes) into the payment for the application of the skin substitute, resulting in a single payment to the provider that includes both the application of the product and the product itself. There is one bundled payment amount for procedures that involve high cost products, i.e., products whose cost exceeds a threshold amount, and another bundled payment amount for procedures that involve low cost products that do not meet the threshold. The bundled payment rate is updated annually and is also geographically adjusted. The bundled payment rates change every year as do the thresholds that determine which products are assigned to the high cost bundle. Currently, all of our currently marketed wound care products are assigned to the high cost bundle; it is not possible to predict, however, whether those products will continue to be assigned to the high cost bundle or the rates that will be paid for each bundle. Further, under the bundling policy there is an inherent incentive to use the cheapest products available, even if those products are less effective. The bundled payment rates are also geographically adjusted. This geographic adjustment may result in significant payment variations among regions; for example, sixty percent of the hospital payment rate is adjusted to take into account the region’s wage-index, which can vary widely from one region to another. The wage-index adjustment may result in reimbursement being insufficient to account for the cost of skin substitute products and sizes in one geographic area that are fully reimbursed in other geographic areas. While we do not expect any changes for calendar year 2020, CMS has previously considered: (i) making changes to the methodology for calculating the thresholds for the low and high cost bundles, (ii) switching to an “episode-based” payment for wound care treatment and (iii) eliminating the low and high cost bundles and instead using a single payment category. The proposed changes described above could result in: (i) our products shifting from the high cost bundle to the low cost bundle or (ii) a decrease in the rate of reimbursement for our products, either of which could have a material adverse effect on our business and the results of our operations.

Interruptions in the supply of our products or inventory loss may adversely affect our business, results of operations and financial condition.

Our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements including stability requirements or specifications. Most of our products must be stored and transported within a specified temperature range. For example, if environmental conditions deviate from that range, our products' remaining shelf-lives could be impaired or their safety and efficacy could be adversely affected, making them unsuitable for use. These deviations may go undetected. The occurrence of actual or suspected production and distribution problems can lead to lost inventories, and in some cases recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays and result in substantial additional expenses. Production of our Affinity product, for example, was suspended in the first quarter of 2019 due to production issues at one of our suppliers. Although our supplier has implemented certain corrective measures, we have determined that the current process does not meet our production standards. As a result, we identified an alternate supplier, but do not expect this new supplier to commence production until the end of the first quarter of 2020 at the earliest. This disruption in supply will result in reduced Affinity revenue. Although we plan to increase production of our other products in order to meet the demand created by the shortage of our Affinity product, there can be no assurance that we will be able to replace, in whole or in part, lost Affinity revenue caused by this production suspension. This and any other unforeseen failure in the storage of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations.

Our ability to use our net operating loss carryforward may be subject to limitation.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income. Specifically, this limitation may arise in the event of a cumulative change in our ownership of more than 50.0% by value within a three-year period. Any such annual limitation may significantly reduce the utilization of our net operating loss carryforwards before they expire. The closing of this offering, alone or together with transactions in our stock that have occurred in the past and may occur in the future, may trigger an ownership change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset our taxable income, if any. Any such limitation, whether as the result of this offering, sales of our common stock by our existing stockholders or additional sales of our common stock by us after this offering, could potentially result in increased tax liability to us in future years. We have fully reserved our net operating loss carryforwards due to uncertainty that we will realize any benefit from them.

The Company's certificate of incorporation and bylaws designate the Court of Chancery of the State of Delaware, to the fullest extent permitted by law, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by the Company stockholders, which could limit the ability of the Company stockholders to obtain a favorable judicial forum for disputes with the Company or with directors, officers or employees of the Company and may discourage stockholders from bringing such claims.

Under the Company's certificate of incorporation and bylaws, unless the Company consents in writing to the selection of an alternative forum, the sole and exclusive forum will be the Court of Chancery of the State of Delaware for:

- any derivative action or proceeding brought on behalf of the Company;
- any action asserting a claim of breach of a fiduciary duty owed by, or any wrongdoing by, any director, officer or employee of the Company to the Company or the Company's stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation (including as it may be amended from time to time), or the bylaws;
- any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or
- any action asserting a claim governed by the internal affairs doctrine, in each case, except for, (1) any action as to which the Court of Chancery determines that there is an indispensable party not subject to the personal jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination) and (2) any action asserted under the Securities Exchange Act of 1934, as amended, or the rules and regulations promulgated thereunder, for which federal courts have exclusive jurisdiction.

These provisions of the Company's certificate of incorporation and bylaws could limit the ability of the Company stockholders to obtain a favorable judicial forum for certain disputes with the Company or with its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and employees. Alternatively, if a court were to find these provisions of the Company bylaws inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings listed above including, without limitation, any actions asserted under the Securities Act of 1933, as amended, the Company may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect its business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit number	Description
3.1	Certificate of Incorporation of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
3.2	Bylaws of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
10.1	Warrant Exchange Agreement dated as of July 12, 2019 by and among Organogenesis Holdings Inc., Avista Capital Partners IV L.P., Avista Capital Partners IV (Offshore), L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on July 16, 2019)
10.2	Letter Agreement dated as of August 6, 2019 by and among Organogenesis Inc., Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC and 65 Dan Road SPE LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 8, 2019)
10.3	Amended and Restated Subordination Agreement dated as of August 6, 2019 by and among Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC, 65 Dan Road SPE LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 8, 2019)
10.4	Amendment No. 1 to Warrant Agreement, dated as of August 19, 2019, by and between the Organogenesis Holdings Inc. and Continental Stock Transfer & Trust Company. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 19, 2019)
31.1†	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2†	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS†	XBRL Instance Document XBRL
101.SCH†	XBRL Taxonomy Extension Schema Document
101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document

† *Filed herewith*

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 12, 2019

Organogenesis Holdings Inc.

(Registrant)

/s/ Timothy M. Cunningham

Timothy M. Cunningham
Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gary S. Gillheeney, Sr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Organogenesis Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [omitted];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

By: /s/ Gary S. Gillheeney, Sr.
Gary S. Gillheeney, Sr.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy M. Cunningham, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Organogenesis Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [omitted];

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

By: /s/ Timothy M. Cunningham
Timothy M. Cunningham
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned officers of Organogenesis Holdings Inc. (the "Company") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2019

By: /s/ Gary S. Gillheeney, Sr.
Gary S. Gillheeney, Sr.
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2019

By: /s/ Timothy M. Cunningham
Timothy M. Cunningham
Chief Financial Officer
(Principal Financial and Accounting Officer)